

### REMARKS

#### **I. Examiner Interview. Amendments.**

Applicants thank the Examiners for the courtesy of the telephone interview held on April 20, 2004.

Applicants have amended the claims in accordance with the Examiners' recommendations. In this regard, claims 29 and 33 have been amended to more clearly recite the structure of the claimed pharmaceutical formulation. Claim 35 has also been amended to recite the administration of a pharmaceutical formulation comprising a core and core materials, wherein the core materials comprise therapeutically effective amounts of a bile acid binder and optional pharmaceutically acceptable excipients, and wherein the core material comprising the bile acid binder is coated with a layer for targeted release of the bile acid binder in the colon. Support for amended claims 29, 33, and 35 is found on page 11, lines 25-27 of the specification.

Claims 34 and 35 have been amended by the deletion of the term "prophylaxis". Accordingly, these claims are now only directed to the therapeutic treatment of a subject suffering from the recited indications.

Upon entry of this Amendment, claims 29 and 33-45 remain pending. No new matter has been added.

#### **II. Rejection under 35 U.S.C. §112, first paragraph**

Claims 34 and 35 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner alleges that the disclosure provides teachings regarding treatment but not complete prevention of the recited disorder.

Claims 34 and 35 have been amended by the deletion of the term "prophylaxis". Withdrawal of the rejection is therefore respectfully requested.

#### **III. Rejections under 35 U.S.C. §112, second paragraph**

Claims 29 and 33-45 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner alleges that the phrase "wherein the bile acid binder is coating layered for targeted release" in claims 29 and 33-35 is unclear. It appears that the Examiner

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made a typographical error in including claim 34 in the rejection, as claim 34 does not recite the quoted language.

Applicants have amended claims 29, 33, and 35 to more clearly recite the structure of the bile acid binder having targeted release properties. Specifically, amended claims 29 and 33 recite that the bile acid binder is a core material of a formulation and that the core material comprising the bile acid binder is coated with a layer for targeted release of the bile acid binder in the colon. Amended claim 35 recites that the bile acid binder is a core material of a formulation and that the core material comprising the bile acid binder is coated with a layer for targeted release of the bile acid binder in the colon.

Accordingly, Applicants submit that amended claims 29, 33, and 35 are clear and definite. Withdrawal of the rejection of claims 29 and 33-45 is requested.

### CONCLUSION

Upon entry of this Amendment, claims 29 and 33-45 remain pending. Applicants respectfully submit that claims 29 and 33-45 are in condition for allowance. Prompt issuance of a Notice of Allowance is earnestly solicited.

The Assistant Commissioner is hereby authorized to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: April 21, 2004

Respectfully submitted,

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